# 60th Medical Group (AMC), Travis AFB, CA

## INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

### FINAL REPORT SUMMARY

### (Please type all information.  Use additional pages if necessary.)

**PROTOCOL #:** FDG20150002A                    **DATE:** 10 September 2015

**PROTOCOL TITLE:** "Partial Resuscitative Endovascular Balloon Occlusion of the Aorta (P-REBOA) in a pig model (Sus scrofa)."

**PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC):** Maj Lucas Neff

**DEPARTMENT:** General Surgery                    **PHONE #:** 423-5179

**INITIAL APPROVAL DATE:** 20 November 2014        **LAST TRIENNIAL REVISION DATE:** N/A

**FUNDING SOURCE:** internal O&M funding

1.    **RECORD OF ANIMAL USAGE:**

| Animal Species: | Total # Approved | # Used this FY | Total # Used to Date |
|---|---|---|---|
| Sus scrofa | 18 | 18 | 18 |
| | | | |
| | | | |

2.    **PROTOCOL TYPE / CHARACTERISTICS:** (Check all applicable terms in **EACH** column)

| | | |
|---|---|---|
| ___ Training: Live Animal | ___ Medical Readiness | ___ Prolonged Restraint |
| ___ Training: non-Live Animal | ___ Health Promotion | ___ Multiple Survival Surgery |
| ___ Research: Survival (chronic) | ___ Prevention | ___ Behavioral Study |
| _x_ Research: non-Survival (acute) | ___ Utilization Mgt. | ___ Adjuvant Use |
| ___ Other (          ) | ___ Other (Treatment   ) | ___ Biohazard |

3.    **PROTOCOL PAIN CATEGORY (USDA):** (Check applicable)    ___ C    ___ D    ___ E

4.    **PROTOCOL STATUS:**

> **\*Request Protocol Closure:**
>
> ___ Inactive, protocol never initiated
>
> ___ Inactive, protocol initiated but has not/will not be completed
>
> _x_ Completed, all approved procedures/animal uses have been completed

5.    **Previous Amendments:**
List all amendments made to the protocol..  **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

| Amendment Number | Date of Approval | Summary of the Change |
|---|---|---|
| 1 | 18 Dec 14 | Procedures, Biosample(s), Protocol title/objective/design |
| 2 | 19 Feb 15 | Procedures, Biosample(s), Protocol title/objective/design |
| 3 | 21 May 15 | Personnel |

6.    **FUNDING STATUS:**    Funding allocated: $         Funds remaining: $

7.    **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review?        _X_ Yes      ___ No

If yes, complete the following sections (Additions/Deletions).  For additions, indicate whether or not the IACUC has approved this addition.

**ADDITIONS:** (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

Dr. Sarah Ashley Ferencz – AI- Yes

**DELETIONS:** (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

None

8.    **PROBLEMS / ADVERSE EVENTS:**  Identify any problems or adverse events that have affected study progress.  Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

None.

9.    **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

**REPLACEMENT (ALTERNATIVES):**  Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No

**REFINEMENT:**  Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No

**REDUCTION:**  Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No

10.    **PUBLICATIONS / PRESENTATIONS:**  (List any scientific publications and/or presentations that have resulted from this protocol.  Include pending/scheduled publications or presentations).
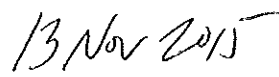
Oral Presentation at the 2015 Annual Meeting of the American Association for the Surgery of Trauma and Clinical Congress of Acute Care Surgery in Las Vegas, NV.

11.    **Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?**

Yes, this study represents a foundation for future combat casualty care project and therapies.

12.    **PROTOCOL OUTCOME SUMMARY:**  (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

_____               13 Nov 2015

      (PI / TC Signature)                        **(Date)**

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**Attachments:**
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission (Mandatory)

**Attachment 1**
**Defense Technical Information Center (DTIC) Abstract Submission**
This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Background: Partial REBOA (P-REBOA) may permit longer periods of occlusion by allowing some degree of distal perfusion. However the ability of this procedure to limit exsanguination is unclear. We evaluated the impact of P-REBOA on immediate survival in a highly lethal swine liver injury model.

Methods: Fifteen Yorkshire-cross swine were anesthetized, instrumented, splenectomized, and subjected to 30% liver amputation. Coagulopathy was created through hemodilution. Randomized swine received no intervention (control), P-REBOA, or complete REBOA (C-REBOA). Central mean arterial pressure (cMAP), carotid blood flow, and blood loss were recorded. Balloons remained inflated in the P-REBOA and C-REBOA groups for 90m followed by graded deflation. The study ended at 180m from onset of hemorrhage or death of the animal. Survival analysis was performed.

Results: Survival times in the control, P-REBOA, and C-REBOA groups were, 25±21, 86±40, and 163±20m, respectively ($p<0.001$). There was no difference in blood loss among the groups. P-REBOA maintained near-baseline carotid blood flow and cMAP, while C-REBOA generated extreme cMAP and prolonged supraphysiologic carotid blood flow. Both experimental groups experienced profound decreases in cMAP following deflation.

Conclusions: With severe ongoing hemorrhage, P-REBOA increased survival time while maintaining cMAP and carotid flow at physiologic levels.

**Grant Number:**_____
**From:**_____
**\*\*If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**

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